REMARKS

Claims 1-14 are pending in this Application. Though no amendments have been made to the claims, Applicant respectfully provides the above claim listing for the Examiner's convenience. Applicant Respectfully thanks the Examiner for finding the previously filed traversal to be persuasive. The Examiner's objections and rejections will now be respectfully addressed in turn.

Rejections under 35 U.S.C. 112 first paragraph

The Examiner rejects claims 1-14 under 35 U.S.C. 112, first paragraph for allegedly failing to comply with the enablement and written description requirements. Applicant respectfully traverses on both counts.

Enablement requirement

Compliance with the enablement requirement is determined commensurate with the scope of each claim (MPEP 2164 .08). Thus, a Specification must teach those skilled in the art how to make and use each element of each claim (each claim taken as a whole) without 'undue experimentation,' unless said elements are well know or inherent in the art. A patent need not teach, and preferably omits, what is well known in the art. *In re Buchner*, 929 F.2d 660, 661, 18 USPQ2d 1331, 1332 (Fed. Cir. 1991) (MPEP 2164.01).

Accordingly, we must analyze claims 1 and 11 (the independent claims) individually. Beginning with claim 1, there is recited a) an intravascular stent with coated inner surfaces, b) an enzyme capable of catabolizing cholesterol and lipids, and c) cells that have been genetically modified to produce such an enzyme. In order to be enabling, each of these elements must be taught in the Specification or known in the art. Part a) is sufficiently disclosed in the Specification (please see pages 2-3 of Applicant's disclosure). Parts b) and c) are identified in an exemplary manner in the Specification as LPL and HUVEC respectively. Regarding the relationship between such exemplary disclosure and the enablement requirement, Applicant respectfully references MPEP 2164.01(b), which states that,

"As long as the specification discloses at least one method for making and using the claimed invention that bears a reasonable correlation to the entire scope of the claim, then the enablement requirement of 35 U.S.C. 112 is satisfied. *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970). Failure to disclose other methods by which the claimed invention may be made does not render a claim invalid under 35 U.S.C. 112. *Spectra-Physics, Inc. v. Coherent, Inc.*, 827 F.2d 1524, 1533, 3 USPQ2d 1737, 1743 (Fed. Cir.), *cert. denied*, 484 U.S. 954 (1987). MPEP 2164.01(b)

Accordingly, as each element in claim 1 is sufficiently described (at least by the above discussed examples) the enablement rejection as it pertains to claim 1 is respectfully overcome.

In fact, Applicant respectfully points out that the Examiner's language at the bottom of page 3 to page 4 in the Office Action is directed to treatment or prevention of disease. Thus, the Examiner's rejection seems to be directed ***solely*** to claim 11. A rejection of claim 11 will therefore now be individually addressed.

Referring to the Examiner's comments at page 3, penultimate paragraph, it is stated that,

"The art at the time of filing did not teach how to use genetically modified cells encoding an enzyme capable of catabolizing cholesterol and lipids to treat or prevent disease."

Applicant respectfully asserts that such a failing by the prior art merely provides evidence of novelty regarding the treatment recited in claim 11.

The Examiner goes on to state,

"Nor did the art at the time of filing teach how to use a vector encoding such an enzyme in the absence of genetically modified cells (direct injection of a vector or plasmid) to treat or prevent disease so that one of skill could guess how to use genetically modified cells encoding such and enzyme. Accordingly, it was unpredictable how to target cells of interest using

genetically modified cells expressing an enzyme capable of catabolizing cholesterol and lipids to treat or prevent disease."

In response, Applicant first respectfully points out that Applicant's Specification describes an exemplary embodiment for using a vector encoding of "such an enzyme" (e.g. LPL) by inserting it into human normal umbilical vein endothelial cells (HUVEC) cells by way of an adeno-associated virus (AAV). Please see Part 2, page 7, line 18 to page 9, line 16 of Applicant's disclosure. The description also particularly refers to the following article: Russell, D.W., and Hirata, R.K. (1998), Human gene targeting by viral vectors. Nat. Genet. 18: 325-330, see Abstract of D5 (enclosed), which provides evidence that one of ordinary skill in the art would have had knowledge of the above discussed usage.

Second, as a further example of such evidence, Applicant respectfully attaches D6 and D7. D6 and D7 were published before the priority date of the present application and describe further possibilities to stably insert LPL vectors into cells, e.g. using myeloproliferative sarcoma virus (MPSV)-based retroviral vectors.

Referring now to the first paragraph on page 4 of the Office Action, the Examiner further states that,

"The specification does not teach where to insert the stent, the amount of LPL expressed, the amount of LPL required to treat or prevent disease or how to target the LPL to the tissues of interest such that disease is treated or prevented. Without such guidance, the specification fails to overcome the unpredictability in the art to use the stent comprising genetically modified cells expressing LPL to treat or prevent disease."

As to the location of the stent, Applicant respectfully points out that the description clearly refers to "intravascular stent," "coronary and peripheral blood vessels" (page 5, lines 22-25, claim 11), and to the fact that "The stent is typically inserted by catheter into a vascular lumen…" (page 2, line 4). One of ordinary skill in the art at that time was therefore aware of an

area for potential insertion of a stent (i.e. at any suitable location in veins and arteries and in particular in the coronary artery), such as the left descending coronary artery. Applicant respectfully attaches evidence of such in D1 and D2 (abstracts). Applicant also respectfully asserts that the amount of LPL required was also known before Applicant's priority date, as is evidenced in D8 (abstract attached). D8 further describes that the amount of LPL actually expressed could have been readily measured one of ordinary skill at the time of the invention.

Third, as the LPL is targeted to the tissues of interest simply by providing LPL on the inner surface of a stent and inserting this stent in the desired location, prevention of restenosis or treatment of obstructive artheriosclerotic lesions by "*address*(ing) *the re-accumulation of lipids in the vein after the stent has been put in place,*" (page 4, lines 8-9 of Applicant's disclosre), is sufficiently known/described.

Accordingly, for at least the above reasons, Applicant respectfully submits that claims 1-14 are in compliance with the enablement requirement of 35 U.S.C 112 first paragraph. Applicant respectfully requests removal of said rejection.

Written description requirement

In order to comply with the written description requirement of 35 U.S.C. 112 first paragraph, a disclosure must demonstrate that an Applicant has possession of the claimed invention. Referring now to the penultimate paragraph of page 4 of the Office Action, the Examiner states that,

"The phrase enzyme "capable of catabolizing cholesterol and lipids" lacks written description. The phrase is mentioned on pg 4, but the only enzyme disclosed in the specification or the prior art of record that catabolizes cholesterol and lipids is lipoprotein lipase (LPL). Therefore, the claims should be limited to LPL."

In response, Applicant respectfully points out that written description rejections are

typically made in response to an amendment to a claim that allegedly includes new matter. Applicant respectfully notes that such an allegation is not being made here, as the claims have not been amended to include subject matter that was not present in the original claims. Under U.S. law there is a strong presumption that an adequate written description of the original claims is present when the application is filed (MPEP 2163 I A). Our mention of an "enzyme capable..." in the claims and the exemplary description provided thereof (LPL discussion in the Applicant's disclosure) should be sufficient to satisfy this presumption, and demonstrate possession of the invention. In fact, as the Examiner correctly states that the description as filed contains the phrase used in the claims, Applicant respectfully submits that this rejection does not include any substantive dispute. The "enzyme capable of…" is present and discussed in the original Application, and therefore should not be rejected for non-compliance with the written description requirement.

Accordingly, for at least the above reasons, Applicant respectfully submits that claims 1-14 are in compliance with the written description requirement of 35 U.S.C 112 first paragraph. Applicant respectfully requests removal of said rejection.

With regards to any potential prior art rejections, Applicant respectfully notes that the claims are novel and non-obvious over the cited art.

Conclusion

The foregoing is believed to be fully responsive to the outstanding Office Action. A Notice of Allowance is respectfully requested.

The Examiner is invited to contact Applicant's attorney at the below-listed phone number regarding this Response or otherwise concerning the present application.

Applicant hereby petitions for any extension of time necessary under 37 C.F.R. §§1.136(a) or 1.136(b).

If there are any charges due with respect to this Amendment or otherwise, please charge them to Deposit Account No. 06-1130 maintained by Applicant's attorneys.

Respectfully submitted,

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